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10/820,844	04/09/2004	Tetsuro Yamate	030486	8680

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WASHINGTON, DC 20036

EXAMINER

METZMAIER, DANIEL S

ART UNIT	PAPER NUMBER
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1796

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01/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/820,844

Applicant(s)

YAMATE, TETSURO

Examiner

Daniel S. Metzmaier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 5-18 are pending.

#### ***Claim interpretation***

1. To the extent the claims employ the language: "included and "containing", said terms have been interpreted to have the same scope as "comprising". See MPEP 2111.03. It is noted that none of the claims define any concentrations.

The claimed compositions, claims 5-9, set forth a proviso that "wherein the chemiluminescent composition induces chemiluminescence when being mixed with an oxidizing composition comprising hydrogen peroxide". The claims employ open transitional language, i.e., "comprising". Said compositions read on intermediate compositions employing both the oxalate/fluorescent component and the activator component since the addition of more activator would be expected to induce some chemiluminescence and the claims do not define the degree of extent said compositions induce the chemiluminescence.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5-6, 9-11 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. It is unclear where applicants provide *ipso verba* basis for compositions having "an acetyltributylcitrate as a major organic solvent" as now claimed in claims 5-6, 9-11 and 14-18.

Original claim 1 does not define said range *per se*. Applicants have not point out the disclosure of said range and the examiner is unable to find the characterization of said range in the original specification disclosing compositions as now claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 5-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 5 and 10 to employ "an acetyltributylcitrate as a major organic solvent". It is unclear how "major organic solvent" is to be interpreted, e.g., concentration, solvating effect, solvent function of a particular solute, advantageous biodegradation effect, etc..

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Cranor, US 7,052,631. See example 4. Attention is further directed to above rejection under 35 USC 112, 2<sup>nd</sup> ¶. Claims 7, 8, 12 and 13 are included herein since the application does not define the phrase "major organic solvent".

8. Claims 5-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Cranor, US PG PUB 2003/0102467. See example 4. Attention is further directed to above rejection under 35 USC 112, 2<sup>nd</sup> ¶. Claims 7, 8, 12 and 13 are included herein since the application does not define the phrase "major organic solvent".

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cranor, US 7,052,631, or US PG PUB 2003/0102467, individually as applied to claims 5-14 above, and further in view of Zweig et al, US 3,729,426; Roberts et al, US 3,701,738; and/or Crigg, US 3,560,395.

Basis for the rejection can be found in paragraph 11 of the Office Action mailed 29 June 2007 and is herein incorporated by reference.

Furthermore, Cranor discloses the example 4 compositions employing acetyltributyl citrate (ATBC) as a device that disintegrates and biodegrades as

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contrasted with other examples, which employ phthalates that either only partially biodegrade (examples 2-3) or do not biodegrade (example 1). Cranor (examples 4 further teaches that naturally occurring bacteria will consume the polymer and solvent combinations in a reasonable period of time.

Cranor discloses the replacement of phthalate solvents with ATBC. Applicants' evidence submitted merely shows the optimization of the use of ATBC solvent that can be determined by routine experimentation as clearly taught and/or at least suggested in the Cranor references.

11. Claims 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omniglow Corporation, WO 94/19421, as applied to claims 5-6 above, and further in view of Zweig et al, US 3,729,426; Roberts et al, US 3,701,738; and/or Crigg, US 3,560,395. Omniglow Corporation (examples, tables and claims) discloses the use of cetyl citrate esters with benzoates (WO '421, claims 1 and 6).

Basis for the rejection can be found in paragraph 12 of the Office Action mailed 29 June 2007 and is herein incorporated by reference.

Furthermore, Omniglow Corporation discloses the (page 4, lines 4-5; and page 5, lines 5-17) specific use of acetyltributyl citrate (ATBC) as a alternative to the phthalates when a phthalate free composition is desired. Omniglow Corporation further teaches that phthalates are undesirable.

Omniglow Corporation discloses the replacement of phthalate solvents with ATBC. Applicants' evidence submitted merely shows the optimization of the use of

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ATBC solvent that can be determined by routine experimentation as clearly taught and/or at least suggested in the Omniglow Corporation reference.

***Response to Arguments***

12. Applicant's arguments filed 01 October 2007 have been fully considered but they are not persuasive.

13. Applicants assert basis for the amendments but said basis is not deemed proper for the claim amendments since they recite specified concentrations rather than the broad range as now claimed.

14. Applicants assert the Cranor references employ a 50/50 mixture of propylene glycol dibenzoate and ATBC. It is unclear that this is distinct from the broad claim language. See applicants' definition of major in arguments at page 7, wherein it is characterized as "greater in number, extent, or importance". See above rejection under 35 USC 112, 2nd ¶.

It is noted, any alleged evidence of unexpected results are not probative for a rejection under anticipation.

Regarding the rejection under 35 USC 103(a), see also MPEP 2144.05(I) wherein it sets forth, "A *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. ***Titanium Metals Corp. of America v. Banner***, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)."

Regarding the claim limitations of 7, 8, 12, 13, 17 and 18; applicants claims and specification do not clearly set forth the major organic solvent is "major in number, major in extent (extent is unspecified), or major in importance (importance is unspecified).

15. Applicants (table 3) examples have not been deemed probative since the effect is shown to be linear and amounts to optimizing the disclosed use of the ATBC of Cranor as a solvent requiring no more than routine experimentation.

16. Applicants' Declaration evidence (item 5) states that the Omniglow Corporation reference at table 1 discloses the use of tributyl citrate as a suitable solvent.

Applicants' Declaration evidence is not deemed to compare the Omniglow Corporation reference compositions since they employ butyl benzoate as a solvent for the fluorescent/oxalate component.

Applicants (page 9) assert Cranor teaches biodegradability but does not teach luminescent intensity and decay of the intensity, which is further asserted to be unexpected. Some variation would have been expected. Differences alone are inadequate to establish nonobviousness; the differences must be statistically significant, unexpected and of practical significance. See, for example, *In re Merck & Co. Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Freeman*, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973).

17. Applicants (pages 9 to 13) assert the 37 CFR 1.132 declaration evidence submitted shows a distinction between the various citrate esters. This has not been deemed persuasive for the following reasons:



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18. The comparison has not been made with the butyl benzoate as employed in the Omniglow reference. See examples 8 and 9 for the oxalate/fluorescent component. Referring to Table 3 of the instant specification, the examples have not been deemed probative since the effect is shown to be linear and amounts to optimizing the disclosed use of the ATBC of the Omniglow reference as a solvent replacement for phthalates requiring no more than routine experimentation.

The results are not commensurate in scope and applicant has not set forth why said data would be extrapolated to the full scope of the claims, which lack concentration, (with the exception of 9 and 14) a specific oxalate species, a specific fluorescent material.

Furthermore, differences alone are inadequate to establish nonobviousness; the differences must be statistically significant, unexpected and of practical significance. See, for example, *In re Merck & Co. Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Freeman*, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973).

19. Applicants further assert the declaration evidence shows comparative performance and should be considered unexpected since Omniglow lacks a citrate in the oxalate/fluorescent component but teaches citrate for the activator component. This has not been deemed persuasive since Omniglow clearly suggest the use of citrates in the oxalate/fluorescent component and applicant's evidence does not rebut said suggestion for the reasons already addressed.

Furthermore, applicant's (pages 9 and 10) arguments regarding the lack of an example in the Omniglow reference to citrates in the oxalate component have not been deemed persuasive since all disclosures in a reference must be considered for what it fairly teaches those of ordinary skill in the art, not just preferred embodiments or specific working examples. In re Boe, 355 F2d 961, 148 USPQ 507, (CCPA, 1966). In re Chapman, 357 F2d 418, 148 USPQ 711, (CCPA, 1966). In re Mills, 470 F2d 649, 176 USPQ 196, (CCPA, 1972). Omniglow clearly teaches and suggest phthalate free combinations as well as citrate solvents therefore.

### ***Conclusion***

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

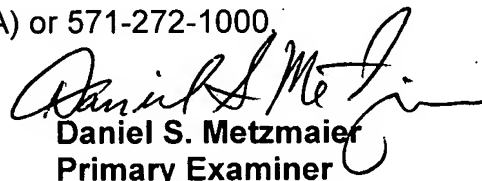
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Daniel S. Metzmaier  
Primary Examiner  
Art Unit 1796

DSM